

Application No. 10/538,542

RCE and Amendment filed April 12, 2010

RCE and Amendment in Response to Final Office Action dated March 2, 2010

REMARKS

After entry of this Amendment, the pending claims are: claims 1, 5, 9, 10, 12-18 and 21. The Final Office Action, dated March 2, 2010, has been carefully considered. Claims 2-4, 6-8, 11, 19 and 20 were previously canceled. Independent claim 1 has been amended to make explicit what was already implicit. Claim 21 has been added. Support for the amendments to claim 1 and newly added dependent claim 21 can be found throughout the Specification and Drawings and specifically in paragraph No. 21 and Fig. 1. Accordingly, no new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following remarks is respectfully requested.

In the Final Office Action, dated March 2, 2010, the Examiner:

- rejected claims 1, 5, 9, 10 and 12 under 35 U.S.C. 103(a) as being unpatentable over U.S. Published Patent Application No. 2004/0106998 to Ferree (“Ferree”) in view of U.S. Patent No. 5,333,347 to Stranders (“Stranders”) in further view of U.S. Published Patent Application No. 2003/0233145 to Landry *et al.* (“Landry”); and
- rejected claims 13-18 under 35 U.S.C. 103(a) as being unpatentable over Ferree in view of Stranders in further view of Landry in further view of U.S. Published Patent Application No. 2002/0052656 to Michelson.

Applicants respectfully traverses these rejections.

INDEPENDENT CLAIM 1

Independent claim 1 is directed to an intervertebral implant comprising a central axis, an upper section, suitable for laying onto a base plate of a vertebral body lying above, and a lower section suitable for laying onto a cover plate of a vertebral body lying below, and recites, *inter alia*, as follows

(emphasis added):

the *upper section* has ... a bottom surface and a first projection extending from the bottom surface, the first projection including a first drill hole ... the *lower section* has ... a top surface and second and third projections extending from the top surface, the second and third projections including second and third drill holes ... and a *frame shaped, central joint section* located between the upper and lower sections so that the upper section is moveable with respect to the lower section, the central joint section including a central bore and ***first, second, third and fourth drill holes***, the first projection extending from the bottom surface of the upper section being receivable within the central bore formed in the central joint section, the central joint section being receivable between the second and third projections extending from the top surface of the lower section so that a ***first axle*** is receivable in the first and second drill holes formed in the central joint section and the first drill hole formed in the first projection, a ***second axle*** is receivable in the third drill hole formed in the central joint section and the second drill hole formed in the second projection and a ***third axle*** is receivable in the fourth drill hole formed in the central joint section and the third drill hole formed in the third projection ...

Ferree discloses an intervertebral implant including upper and lower plates. As admitted by the Examiner, Ferree does not disclose, teach or suggest the features recited above. *See Final Office Action*, dated March 2, 2010, pages 3 and 4. As such, the Examiner relies on Stranders for disclosing those features. *See Final Office Action*, dated March 2, 2010, page 5.

Stranders discloses an apparatus for cleaning the inner surfaces of the front and rear windows of an ***automobile***. The apparatus includes a handle (1) and a cleaning part (2) wherein the handle (1) is connected to the cleaning part (2) via a knuckle joint (5). In use, the knuckle joint (5) provides limited mobility of the handle (1) relative to the cleaning part (2).

Applicants respectfully submit that it would not be obvious for one of ordinary skill in the art to utilize the ***automotive*** knuckle joint of Stranders in the ***artificial spinal disc*** of Ferree. First and foremost, Stranders does not disclose a first, second and ***third*** axle; rather, Stranders at most discloses a

first and second axle. As shown in the figure in the Final Office Action, Stranders discloses at most a unitary “second” axle which the Examiner has labeled both “second” and “third” axles (indicating each half as being a single element). *Final Office Action*, dated March 2, 2010, pages 3.

Next, the automotive knuckle joint of Stranders is designed for operation under different conditions – the claimed invention is designed for operation and articulation within the spinal column of the human body; in contrast, the wiper of Stranders is designed for operation and articulation while cleaning a windshield by hand. Further, an intervertebral implant typically experiences large forces associated with the human spine. In addition, an intervertebral implant typically allows sufficient rotational movement of the upper and lower sections (i.e., plates or members). A windshield wiper is not concerned with such issues or forces. The ordinary person of skill in the art of making intervertebral implants would not look to handheld windshield wipers for design features.

Moreover, Stranders is completely silent as to the sufficiency of using the disclosed knuckle joint in an intervertebral implant. Stranders is also completely silent on the ability for the recited joint to withstand the necessary forces experienced within an intervertebral implant. Further, the examiner has not *clearly articulated any reasoning with some rational underpinning* to explain why one of ordinary skill in the art of intervertebral implants would look to windshield wipers when designing spinal implants.

Third, Applicants respectfully submit that, if for some strange reason the ordinary intervertebral implant designer did look towards Strander’s windshield wiper for design features, there is no reason for implementing an implant comprising four drill holes and three axles in the particular manner as recited

by the claims. Specifically, there is no reason for implementing an implant comprising a first drill hole formed in a first projection extending from the bottom surface of the upper section, second and third drill holes formed in second and third projections, respectively, extending from a top surface of the lower section, and first, second, third and fourth drill holes formed in a frame shaped, central joint section wherein the first projection is received within a central bore formed in the frame and the frame is received between the second and third projections so that a first axle is received in the first and second drill holes formed in the frame and the first drill hole formed in the first projection, a second axle is received in the third drill hole formed in the frame and the second drill hole formed in the second projection and a third axle is received in the fourth drill hole formed in the frame and the third drill hole formed in the third projection.

Applicants respectfully submit that in order to reach a proper determination of obviousness under 35 U.S.C. § 103, the Examiner must step backward in time and into the shoes worn by a hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. *See M.P.E.P. § 2142.* This puts the examiner in the time period in which possibly hundreds of intervertebral implant patents have been issued, not a single one of which the examiner has found to include the recited joint. Next, knowledge of the Applicants’ disclosure must be put aside. *See Id.* Although the tendency to resort to “hindsight” based upon the Applicants’ disclosure is often difficult to avoid, impermissible hindsight must nonetheless be avoided. *See Id.*

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. *See M.P.E.P. § 2142.* The Federal Circuit has stated that “rejections on obviousness cannot be sustained with mere conclusory statements;

instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *See In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006); *see also KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007) (quoting *In re Kahn* with approval). The Supreme Court of the United States affirmed this reasoning in *KSR*, stating that the analysis supporting a rejection under 35 U.S.C. §103 should be made explicit. *KSR*, 127 S.Ct. at 1741. Moreover, this Board has followed suit and has observed that the Supreme Court in *KSR* “did not dispense with the premise that a conclusion of obviousness requires some explicit rationale for practicing the claimed subject matter:”

[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Ex parte Coppeta, Appeal 20084898, decided February 5, 2009 (quoting *KSR*, 127 S.Ct. at 1741); *see also Ex parte Zhu*, Appeal 20082138, decided May 19, 2008 (reversing the rejections under 35 U.S.C. §103 because the examiner provided no “apparent reason to combine the known elements in the fashion claimed”); *Ex parte McQuiston*, Appeal 20083224, decided March 6, 2009 (reversing the rejection under 35 U.S.C. §103 because the examiner failed to provide an obviousness rationale); *Ex parte Barnes*, Appeal 20074114, decided Jan. 22, 2009 (reversing the rejection under 35 U.S.C. §103

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because the examiner failed to “provide any reason with rational underpinning to explain why [the feature of the claimed invention] would have been obvious”).

In the present application, the Examiner supports his combination of Stranders with Ferree by stating that the joint of Ferree and the universal joint as taught by Stranders are equivalent for their use in the joints and connections art and the selection of any of these known equivalents to join or connect two parts would be within the level of ordinary skill in the art.

Applicants respectfully submit that the Office Action’s justification for combining Stranders with Ferree does not constitute a ***clear articulated reasoning with some rational underpinning*** for supporting a legal basis for sustaining an obviousness rejection. Rather, the purported justification is merely an unsupported broad conclusory statement, which is precisely the type of justification that the MPEP and courts warn against. It is respectfully submitted, that the Examiner is undertaking and relying on impermissible hindsight reconstruction. Applicants respectfully submit that the Examiner has picked and chosen individual elements from assorted prior art references and has combined the selected elements into a theoretical device that includes all of the elements of the device of claim 1 in a way that one having ordinary skill in the art at the time of the invention would never have combined such elements. The Examiner has provided no support, reasoning and/or evidence for combining the prior art references in this manner, other than the combination would disclose each and every limitation of pending independent claim 1. *See Grain Processing Corp. v. American Maitze-Products Corp.*, 840 F.2d 902 (Fed. Cir. 1988) (one cannot simply use the Applicant’s disclosure as a blueprint to pick and

choose among the individual elements of assorted prior art references in order to combine the right references in the right way to achieve the Applicant's claimed invention).

It is respectfully submitted that without the benefit of the Applicants' disclosure, it would not be obvious for one of ordinary skill in the art to redesign the intervertebral implant of Ferree to include the recited joint as taught by Stranders and any unsupported broad conclusory statement to the contrary to support such a conclusion of obviousness cannot be sustained. Moreover, even if one would have endeavored, for some strange reason, to combine the joint of Stranders with the intervertebral implant of Ferree, the result would not be the invention as claimed. In contrast, the result would be a *two axle* joint, rather than a system having *three axle*, as recited by the claims.

Accordingly, Applicants respectfully submit that the Examiner's combination of Stranders with Ferree to render obvious the claimed invention is in error, and consequently the rejection under 35 U.S.C. § 103(a) cannot stand. Withdrawal of the present rejections and allowance of independent claim 1 is respectfully requested.

Independent claim 1 further discloses an insert for temporary blocking movement of the upper and lower sections, the insert including a lower end and an upper end, the upper end being receivable in the first depression, the lower end being receivable in the second depression.

As admitted by the Examiner, the combination of Ferree and Stranders does not disclose, teach or suggest an insert for causing temporary blocking movement of the upper and lower sections, the ventral sides of the upper and lower sections including first and second depressions, the insert including a lower end and an upper end, the upper end being receivable in the first depression, the lower end being

receivable in the second depression. *See Final Office Action*, dated March 2, 2010, page 5. Rather, the Examiner further relies on Landry for disclosing an insert for temporary blocking movement of the upper and lower sections.

Landry discloses an intervertebral implant 10 including a first implant member (i.e., a top plate or member), a second implant member (i.e., a bottom plate or member) and a plurality of connectors 14 for coupling the first and second implant members. The inner surfaces of the first and second implant members include tapered slots 32 for engaging the plurality of connectors 14. In use, after the implant has been inserted into a patient's intervertebral disc space, the compressive forces applied to the implant deflect the connectors 14 to enable the first implant member of the implant to move a small distance towards the second implant member of the implant. As such, some of the compressive force applied to the implant members may be transferred to bone growth material positioned between the implant members to thereby promote formation of bone that fuses together the vertebrae joined by the implant.

Applicants respectfully submit that there is no disclosure, teaching, or suggestion in Landry, either alone or in combination with Ferree and Stranders, of an insert for temporary blocking movement of the upper and lower sections. Rather, the so-called insert in Landry is a plurality of connectors for permanently coupling the first and second implant members.

Furthermore, in an effort to expedite prosecution of the present application, Applicants respectfully submit that independent claim 1 has amended to make explicit what was already implicit. That is, that the insert is removable from the intervertebral implant after the implant has been inserted within the patient's intervertebral disc space. Applicants respectfully submit that the plurality of connectors in Landry are not removable from the intervertebral implant after the implant has been

inserted within the patient's intervertebral disc space. Rather, as stated in Landry, preferably the large forces are applied to the connectors 14 and the implant members to deform the tapered slots and/or connectors 14 so that removal of the connectors 14 is prevented. See Paragraph 100.

Therefore, Applicants respectfully submit that claim 1 is allowable over Ferree, Stranders and Landry for at least these reasons. Withdrawal of this rejection and allowance of claim 1 is respectfully requested.

Furthermore, as claims 5, 9, 10 and 12-18 all depend from independent claim 1, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 5, 9, 10 and 12-18 is also respectfully requested.

With respect to claims 13-18 which were rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree in view of Stranders in view of Landry and in further view of Michelson, it is respectfully submitted that Michelson does not overcome the short comings of Ferree, Stranders and Landry. Michelson was cited for the proposition that it would be obvious to incorporate at least two holes in the upper and lower section for receiving bone fixation devices. Without addressing the merits of this argument and/or the combination, it is respectfully submitted that, for at least the above-identified reasons, neither Ferree, Stranders, Landry nor Michelson, either alone or in combination, disclose, teach or suggest all of the limitations of dependent claims 13-18 and, specifically, the above-listed features of claim 1. Thus, it is respectfully submitted that dependent claims 13-18 are allowable over Ferree, Stranders, Landry and Michelson. Withdrawal of this rejection and allowance of dependent claims 13-18 is respectfully requested.

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As newly added dependent claim 21 depends from independent claim 1, it is submitted that claim 21 is equally allowable. Allowance of claim 21 is also respectfully requested.

CONCLUSION

Based upon the above-listed amendments and remarks, Applicants respectfully submit that the present application, including claims 1, 5, 9, 10, 12-18 and 21, is in condition for allowance and such action is respectfully requested.

A fee of \$810.00 is believed due for this submission for the filing of a Request for Continued Examination. The Commissioner is authorized to charge this and any other fee which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

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Respectfully submitted,

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